UTAH

PATRICIA KNIGHT
CHIEF OF STAFF

104 Hart Senate Office Building

Telephone: (202) 224-5251
TDD (202) 224-2849

E-mail: senator_hatch@hatch.senate.gov
Website: http://www.senate.gov/~hatch/

United States Senate

WASHINGTON, DC 20510-4402

COMMITTEES:

JUDICIARY
CHAIRMAN

FINANCE
CHAIRMAN, SUBCOMMITTEE ON INTERNATIONAL TRADE

INTELLIGENCE

INDIAN AFFAIRS

JOINT COMMITTEE ON TAXATION

June 13, 2001

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary,

I am writing to express my views regarding federal funding of biomedical research involving human pluripotent[1] embryonic stem cells. After carefully considering the issues presented, I am persuaded that such research is legally permissible, scientifically promising, and ethically proper. Therefore, at this time, I support the use of federal funds to conduct research involving human pluripotent stem cells derived from embryos produced through the in vitro fertilization process. My support is, of course, conditioned upon such research being conducted in strict accordance with the relevant statutes and the protections set forth in the applicable regulations and guidelines, including those issued by the National Institutes of Health (NIH).

I am mindful that this is a matter over which reasonable, fair-minded persons may ultimately disagree. Despite this likely outcome, I believe it constructive for public dialogue to take place over this issue. For that reason, I recommend that you convene the National Institutes of Health Human Pluripotent Stem Cell Review Group (HPSCRG) or a similar expert advisory body to help bring resolution to this matter. The HPSCRG, to be chaired by Dr. James Kushner of the University of Utah, can become a key forum to provide information and advice for policymakers.

At the outset, let me be clear about one of my key perspectives as a legislator: I am pro-family and pro-life. I abhor abortion and strongly oppose this practice except in the

---

[1] "Pluripotent" cells can give rise to most but not all tissues of an organism while "totipotent" cells, such as fertilized eggs, have the potential to develop into a complete organism. In humans, approximately four days after fertilization the totipotent cells form a hollow sphere of cells called a blastocyst and begin to transform into the pluripotent cells which eventually become all the specialized tissues that comprise the human body.

limited cases of rape, incest, and to protect the life of the mother. While I respect those who hold a pro-choice view, I have always opposed any governmental sanctioning of a general abortion on demand policy. In my view, the adoption of the Hyde Amendment wisely restricts taxpayer financed abortions. Moreover, because of my deep reservations about the Supreme Court's decision in *Roe v. Wade*, I proposed – albeit unsuccessfully – an amendment to the Constitution in 1981 that would have granted to the states and Congress the power to restrict or even outright prohibit abortion.

In 1992, I led the Senate opposition to fetal tissue research that relied upon cells from induced abortions. I feared that such research would be used to justify abortion or lead to additional abortions. It was my understanding that tissue from spontaneous abortions and ectopic pregnancies could provide a sufficient and suitable supply of cells. Unfortunately, experts did not find these sources of cells as adequate for their research needs. Subsequently, the 1993 NIH reauthorization legislation changed the legal landscape on this issue.

Because of my strong pro-life beliefs, I am a co-sponsor of the Unborn Victims of Violence legislation that makes it a separate criminal offense to cause death of or bodily injury to unborn children. I also support the Child Custody Protection Act that addresses the problem of minors crossing states lines to obtain abortions in avoidance of home state parental consent or notification requirements. I have also helped lead the effort to outlaw partial birth abortion, a procedure I find to be particularly repugnant. I hope that the 107th Congress will succeed in adopting, and transmitting for the President's signature, legislation that will end late term abortions unless necessary to save the life of the mother.

I am proud of my strong pro-life, anti-abortion record. I commend the Bush Administration for its strong pro-life, pro-family philosophy. In my view research, on stem cells derived from embryos first created for, but ultimately not used in, the process of in vitro fertilization, raises questions and considerations fundamentally different from issues attendant to abortion. As I evaluate all these factors, I conclude that this research is consistent with bedrock pro-life, pro-family values. I note that our pro-life, pro-family Republican colleagues, Senators Strom Thurmond and Gordon Smith, as well as former-Senator Connie Mack, support federal funding of embryonic stem cell research. It is my hope that once you have analyzed the issues, you will agree with us that this research should proceed.

The Legal Framework

After reviewing the relevant statutes and regulations, I conclude that there is no mandatory legal barrier under federal law to federal funding of research on human pluripotent embryonic stem cells. On January 15, 1999, the then-General Counsel of the Department of Health and Human Services, Harriet Raab, issued a legal opinion regarding federal funding for research involving human pluripotent stem cells. This opinion summarized the applicable law as follows:

> The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not within the statutory definition. To the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to the statutory prohibition on sale for valuable consideration, the restrictions on fetal tissue transplantation research that is conducted or funded by HHS, as well as to the federal criminal prohibition on the directed donation of fetal tissue. Research involving human pluripotent stem cells excised from a non-living fetus may be conducted only in accordance with any applicable state or local law. Finally, the Presidential Directive banning federal funding of human cloning would apply to pluripotent stem cells, only if they were to be used for that purpose.[2]

While some take exception to this reading of the law, I believe that it sets forth a permissible interpretation of the current state of the law with respect to research on human pluripotent stem cells. I would also note that while subsequent to the issuance of the HHS Legal Opinion in January, 1999 attempts have been and are being made to change the law, Congress has not passed a bill that has altered the legal status quo. For example, Senator Brownback and others have attempted to change the law to prohibit flatly such research on fetal and embryonic stem cells. On the other hand, Senator Specter and others have supported legislation that would expand the range of permissible federally funded research activities to include derivation of pluripotent stem cells from totipotent stem cells. The considerable disagreement over what the law in this area should

---

[2]Federal Funding for Research Involving Human Pluripotent Stem Cells, Memorandum of Law from Harriet S. Raab, General Counsel, Department of Health and Human Services to Harold Varmus, M.D., Director, National Institutes of Health, January 15, 1999, pp.1-2.

be stands in contrast to the common understanding of how the law has been interpreted by the Department.

It is worth noting that NIH has a carefully crafted network of regulations and guidelines that govern stem cell research. These guidelines, finalized in the *Federal Register*, on August 25, 2000 (65 *FR* 51976) were the subject of over 50,000 public comments. Among the key provisions of these requirements are:

- NIH funds may only be used for research on human pluripotent stem cells derived from embryos, if such cells were derived from frozen embryos that were produced for the purpose of procreation but subsequently were not intended to be used for that purpose.

- No financial or other inducements, including any promises of future remuneration from downstream commercialization activities, may be used to coerce the donation of the embryo.

- A comprehensive informed consent must be obtained that includes recognition that the donated embryo will be used to derive human pluripotent stem cells for research that may include transplantation research; that derived cells may be stored and used for many years; that the research is not intended to provide direct medical benefit solely to a donor and that the donated embryo will not survive the derivation process; and, there must be a distinct separation between the fertility treatment and the decision to donate the embryos for research.

- The donation may not be conditioned on any restrictions or directions regarding the individual who may receive the cells derived from the human pluripotent stem cells.

- All recipients of NIH funds to conduct stem cell research must comply with guidelines and all laws and regulations governing institutional review boards.

- NIH funds may <u>not</u> be used to: clone a human being; derive pluripotent stem cells from human embryos; conduct research using pluripotent stem cells derived from a human embryo created solely for research purposes; conduct research that creates or uses pluripotent stem cells derived from somatic cell nuclear transfer; or, combine human pluripotent stem cells with an animal embryo.

If there is a need to further strengthen the applicable guidelines and regulations, this should be done. But let us recognize that there already exists a thorough and thoughtful regulatory framework to build upon. It should also be noted that these guidelines build upon an extensive body of earlier work of the National Bioethics Advisory Committee, the Advisory Committee to the Director, NIH, and a special Human Embryo Research Panel convened by your predecessor. At this juncture, it appears that NIH is developing its stem cell research policies in an informed fashion within an area of its expertise, and is operating within a statutory environment such that, once finalized, the agency's actions will likely survive legal challenge due to the deference the courts grant these types of decisions.

The Scientific Opportunities

Scientific experts believe that stem cells have tremendous potential in benefitting human health. Stem cells are thought to be a unique biological resource because these cells apparently have the potential to develop into most of the specialized cells and tissues of the body, including muscle cells, nerve cells, and blood cells. As the American Association for the Advancement of Science has characterized the promise of stem cell research: "Research on these cells could result in treatments or cures for the millions of Americans suffering from many of humanity's most devastating illnesses, including Alzheimer's disease, diabetes, spinal cord injury, and heart disease." Potentially, stem cell research can help virtually every American family. It has been estimated that over 128 million Americans are afflicted with conditions that may benefit from embryonic stem cell research.

It is also worth noting in the pro-family context that stem cell research is of particular interest to pediatricians. Consider the views of Dr. Edward B. Clark, Chairman of the Department of Pediatrics, University of Utah School of Medicine:

> "...I can assure you that the scientific promise of stem cell research is extraordinary.
>
> In pediatrics, stem cell research offers therapy, and indeed possibly a cure, for a wide variety of childhood diseases, including neurologic disease, spinal cord injuries, and heart disease...
>
> I can think of nothing that will provide as much meaningful therapy for children and children's problems than the promise offered by stem cell research."

We citizens of Utah are proud to be home of the Huntsman Cancer Institute at the University of Utah. The medical director of the Huntsman Cancer Institute, Dr. Stephen Prescott, advises me that in his expert opinion stem cells research "is an incredibly promising area that has potential application in many different fields of medicine. One of these is in the treatment of cancer, particularly as a way to control the side effects following standard treatments."

I am also aware that some believe, including highly-respected scientists and many of my friends and colleagues in the Right to Life community, that adult stem cells actually hold greater promise than embryonic stem cells and that research on adult stem cells should be pursued to the exclusion of fetal or embryonic stem cells. It is my understanding that, at the present time, the view that adult stem cell research is sufficient or even scientifically preferable to embryonic stem cell research is not the predominant view within the biomedical research community.

While I have great admiration for, confidence in, and strongly support America's biomedical research enterprise, and I believe that our policy should be made on the best science available, I am hardly one who invariably follows the lead of what some may term "the science establishment." With Senator Harkin, I authored the legislation that created the Center for Complementary and Alternative Medicine(CCAM) at NIH and believe there is great benefit in encouraging challenges to scientific orthodoxy. Similarly, I authored the Dietary Supplement Health and Education Act that set parameters on how the Food and Drug Administration may regulate dietary supplements as well as establishing the Office of Dietary Supplements(ODS) at NIH. To be sure, the creation of CCAM and ODS had their fair share of critics at NIH and among mainstream scientists. So be it.

In parallel to funding research on human pluripotent embryonic stem cells, I believe it is essential to carry out significant research on adult stem cells. I strongly urge the Administration to continue to provide sufficient resources to investigate fully the utility of adult stem cells as well cells derived from adipose tissue.

Policymakers should also consider another advantage of public funding of stem cell research as opposed to leaving this work beyond the reach of important federal controls. Federal funding will encourage adherence to all of the safeguards outlined above by entities conducting such research even when a

particular research project is conducted solely with private dollars.

I also think it important to recognize explicitly that the knowledge gained through biomedical research can be harnessed for critical pro-life, pro-family purposes. When one of our loved ones is stricken by illness, the whole family shares in the suffering. The quality of life for America's families can improve as strides are made in biomedical research. This is why we are making good on the bipartisan commitment to double the funding of the NIH research program by 2003. I commend the Administration for its leadership in allocating resources for this worthy pro-life, pro-family purpose.

Ethical Appropriateness

While society must take into account the potential benefits of a given technological advance, neither scientific promise nor legal permissibility can ever be wholly sufficient to justify proceeding down a new path. In our pluralistic society, before the government commits taxpayer dollars or otherwise sanctions the pursuit of a novel field of research, it is imperative that we carefully examine the ethical dimensions before moving, or not moving, forward.

I would hope there is general agreement that modern techniques of in vitro fertilization are ethical and benefits society in profound ways. I have been blessed to be the father of six children and the grandfather of nineteen grandchildren. Let me just say that whatever success I have had as a legislator pales in comparison to the joy I have experienced from my family in my roles of husband, father, and grandfather. Through my church work, I have counseled several young couples who were having difficulty in conceiving children. I know that IVF clinics literally perform miracles every day. It is my understanding that in the United States over 100,000 children to date have been born through the efforts of IVF clinics.

Intrinsic with the current practice of IVF-aided pregnancies is the production of more embryos than will actually be implanted in hopeful mothers-to-be. The question arises as to whether these totipotent embryonic cells, now routinely and legally discarded — amid, I might add, no great public clamor -- should be permitted to be derived into pluripotent cells with non-federal funds and then be made available for research by federal or federally-supported scientists?

Cancer survivor and former Senator, Connie Mack, recently explained his perspective on the morality of stem cell research in a *Washington Post* op-ed piece:

> "It is the stem cells from surplus IVF embryos, donated with the informed consent of couples, that could give researchers the chance to move embryonic stem cell research forward. I believe it would be wrong not to use them to potentially save the lives of people. I know that several members of Congress who consider themselves to be pro-life have also come to this conclusion."

Senator Mack's views reflect those of many across our country and this perspective must be weighed before you decide.

Among those opposing this position is Senator Brownback, who has forcefully expressed his opinion:

> "The central question in this debate is simple: Is the embryo a person, or a piece of property? If you believe ... that life begins at conception and that the human embryo is a person fully deserving of dignity and the protection of our laws, then you believe that we must protect this innocent life from harm and destruction."

While I generally agree with my friend from Kansas on pro-life, pro-family issues, I disagree with him in this instance. First off, I must comment on the irony that stem cell research – which under Senator Brownback's construction threatens to become a charged issue in the abortion debate – is so closely linked to an activity, in vitro fertilization, that is inherently and unambiguously pro-life and pro-family.

I recognize and respect that some hold the view that human life begins when an egg is fertilized to produce an embryo, even if this occurs *in vitro* and the resulting embryo is frozen and never implanted *in utero*. To those with this perspective, embryonic stem cell research is, or amounts to, a form of abortion.[3] Yet this view contrasts with statutes, such as

---

[3] In this regard, I must commend, despite ultimately disagreeing with him, Richard M. Doerflinger, Associate Director for Policy Development, National Conference of Catholic Bishops for his excellent article, "The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint." *Kennedy Institute of Ethics Journal* Vol.9, No.2, 137-150, 1999.

Utah's, which require the implantation of a fertilized egg before an abortion can occur[4].

Query whether a frozen embryo stored in a refrigerator in a clinic is really equivalent to an embryo or fetus developing in a mother's womb? To me, a frozen embryo is more akin to a frozen unfertilized egg or frozen sperm than to a fetus naturally developing in the body of a mother. In the case of in vitro fertilization, extraordinary human action is required to initiate a successful pregnancy while in the case of an elective abortion an intentional human act is required to terminate pregnancy. These are polar opposites. The purpose of in vitro fertilization is to facilitate life while abortion denies life. Moreover, as Dr. Louis Guenin has argued[5]: "If we spurn [embryonic stem cell research] not one more baby is likely to be born." I find the practice of attempting to bring a child into the world through in vitro fertilization to be both ethical and laudable and distinguish between elective abortion and the discarding of frozen embryos no longer needed in the in vitro fertilization process.

In evaluating this issue, it is significant to point out that no member of the United States Supreme Court has ever taken the position that fetuses, let alone embryos, are constitutionally protected persons. To do so would be to thrust the courts and other governmental institutions into the midst of some of the most private of personal decisions. For example, the use of contraceptive devices that impede fertilized eggs from attaching onto the uterine wall could be considered a criminal act. Similarly, the routine act of discarding "spare" frozen embryos could be transformed into an act of murder.

As much as I oppose partial birth abortion, I simply can not equate this offensive abortion practice with the act of disposing of a frozen embryo in the case where the embryo will never complete the journey toward birth. Nor, for example, can I imagine Congress or the courts somehow attempting to order every "spare" embryo through a full term pregnancy.

---

[4] Utah Code Ann. § 76-7-301(1) provides: "'Abortion' means the intentional termination or attempted termination of human pregnancy after implantation of a fertilized ovum, and includes all procedures undertaken to kill a live unborn child and includes all procedures to produce a miscarriage. "Abortion" does not include the removal of a dead unborn child."

[5] Dr. Louis M. Guenin, "Morals and Primordials," *Science*, June 1, 2001.

Mr. Secretary, I greatly appreciate your consideration of my views on this important subject. I only hope that when all the relevant factors are weighed both you and President Bush will decide that the best course of action for America's families is to lead the way to a possible new era in medicine and health by ordering that this vital and appropriately regulated research proceed.

Sincerely,

Orrin G. Hatch
United States Senator